PATENT COOPERATION TREATY Rec'd PCT/PTO 11 APR 2005

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 663988	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/JP 03/13155	International filing date *(day/month/year)* 15.10.2003	Priority date *(day/month/year)* 16.10.2002
International Patent Classification (IPC) or both national classification and IPC A61K9/20		
Applicant TAKEDA PHARMACEUTICAL COMPANY LTD. et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☒ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
27.11.2003	22.02.2005
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Kardas-Llorens, E Telephone No. +49 89 2399-8652

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/JP 03/13155

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-359 as originally filed

Claims, Numbers

1-49 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees, the applicant has:

   ☐ restricted the claims.

   ☐ paid additional fees.

   ☐ paid additional fees under protest.

   ☐ neither restricted nor paid additional fees.

2. ☒ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

   ☐ complied with.

   ☒ not complied with for the following reasons:

   see separate sheet

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

   ☒ all parts.

   ☐ the parts relating to claims Nos. .

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	
	No:	Claims	1-49
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-49
Industrial applicability (IA)	Yes:	Claims	1-49
	No:	Claims	

2. Citations and explanations

   see separate sheet

Re Item IV

Lack of unity of invention

There is no single general inventive concept between independent claims 1, 24 and 41, since they are directed to different inventions as follows:

1. Claims: 1-23

Independent claim 1 describes a capsule comprising a tablet, granule or fine granule, an active ingredient (not explicitly claimed) and a gel-forming polymer.

2. Claims: 24-40

Independent claim 24 describes a tablet, granule or fine granule comprising a core particle containing an imidazole compound (I'), a selected coating polymer which is soluble in the pH range of 6.0 to 7.5.

3. Claims: 41-49

Independent claim 41 describes a capsule comprising;

(I) a tablet, granule or fine granule comprising a core particle containing an imidazole compound (I'), a selected coating polymer which is soluble in the pH range of 6.0 to 7.5 and

(ii) a tablet, granule or fine granule comprising a core particle containing an active ingredient and an enteric coating which is dissolved.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability;

Citations and explanations supporting such statement:

D1: US-B-6 391 342 (HENRIKSEN KRISTIAN LUND ET AL) 21 May 2002 (2002-05-21)

D2: EP-A-0 247 983 (HAESSLE AB) 2 December 1987 (1987-12-02)

D3: WO 03/061584 A (UNIV MISSOURI) 31 July 2003 (2003-07-31)

D4: US 2002/076435 A1 (CHEN SHIH MIN ET AL) 20 June 2002 (2002-06-20)

D5: US-A-5 814 338 (VERONESI PAOLO ALBERTO) 29 September 1998 (1998-09-29)

D6: US-A-6 159 499 (SETH PAWAN) 12 December 2000 (2000-12-12)

D7: WO 98/50019 A (CHEN JIVN REN ;SAGE PHARMACEUTICALS INC (US)) 12 November 1998 (1998-11-12)

D8: EP-A-0 960 620 (RANBAXY LAB LTD) 1 December 1999 (1999-12-01)

D9: DE 198 01 811 A (STADA ARZNEIMITTEL AG) 22 July 1999 (1999-07-22)

D10: US-B-6 306 4351 (CHEN GAN-LIN ET AL) 23 October 2001 (2001-10-23)

D11: WO 02/26210 A (PELLONI CHRISTOPHER L ;CULLEN DAN (US);

GENEVA PHARMACEUTICALS INC) 4 April 2002 (2002-04-04)

D12: US-A-5 817 338 (BERGSTRAND PONTUS JOHN ARVID ET AL) 6 October 1998 (1998-10-06)

D13: US-A-5 840 737 (PHILLIPS JEFFREY OWEN) 24 November 1998 (1998-11-24)

D14: US-A-6 077 541 (CHEN CHIH-MING ET AL) 20 June 2000 (2000-06-20)

Novelty:

The subject-matter of independent claims 1, 24 and 41 is not novel, since being disclosed in documents D1-D14, in each taken alone. For the relevant claims see the indications in each cited document in the search report.

Inventive Step:

According to present page 3, the object of the present invention is to provide a controlled release preparation wherein the release of active ingredient of drug is controlled, which releases an active ingredient for an extended period of time with staying or slowly migrating in the gastrointestinal tract.

This object has been presently solved by the preparations according to claims 1, 24 and 41.

The presently posed problem has been already solved in a similar manner by the teachings of documents D1, D2, D4-D14.

Thus, the solution proposed in claims 1, 24 and 41 of the present application cannot be considered as involving an inventive step (Article 33(3) PCT).

Re Item VI

Certain documents cited

Certain published documents

Application No Patent No	Publication date *(day/month/year)*	Filing date *(day/month/year)*	Priority date *(valid claim)* *(day/month/year)*
WO-A-03061584	31.07.03	17.01.03	19.01.02